Claims

1. A method of preparing a purified, virus inactivated and virus safe antibody preparation from a starting solution comprising antibodies and contaminants, the method comprising the steps of:

   (a) adjusting the pH of the starting solution to about 4.6 to about 4.95, in particular to about 4.8 to about 4.95 to produce an intermediate solution;

   (b) adding caprylate and/or heptanoate ions to the intermediate solution and maintaining the pH at about 4.6 to about 4.95, in particular at about 4.8 to about 4.95, whereby a precipitate is formed and the antibodies are essentially present in the supernatant;

   (c) incubating the supernatant solution under conditions of caprylate and/or heptanoate ion concentration, time, pH and temperature optionally concentrating and diafiltrating the filtrated solution before pH adjustment;

   (d) applying the filtered solution with a least one anion exchange resin and optionally with two different anion exchange resins under conditions that allow binding of contaminants to the resin while not allowing significant binding of the antibodies to the resin, wherein a purified, virus inactivated and virus safe antibody preparation is produced.

2. The method of claim 1 wherein in step (d) the virus inactivated solution is contacted with the at least one anion exchange resin at a pH from about 5.0 to 5.2.

3. The method of claim 1 and/or 2 wherein a second anion exchange chromatography is performed at a pH range of from 6.7 to 6.9.

4. The method of claims 1 to 3 wherein steps (b) and (c) are repeated at least one time.

5. The method of claims 1 to 4 wherein the starting solution comprises plasma-derived antibodies.

6. The method of claims 1 to 5 wherein in step (d) the inactivated solution is contacted with two different anion exchange resins under conditions such

that contaminants are selectively bound to the resins while the antibodies, are not significantly bound to the resins.

7. The method of claims 1 to 6, wherein the antibodies are immunoglobulin G.

8. The method of claim 6, where the pH is adjusted to pH 6.8 ± 0.1 prior to the second anion-exchange chromatography.

9. The method of claims 1 to 8, wherein the anion-exchange chromatography flow-through is concentrated to 60 to 90 mg/ml and diafiltrated against a buffer solution, preferably a phosphate buffer.

10. The method of claims 1 to 9, wherein the flow-through of the first anion-exchange chromatography is solvent detergent treated, preferably by Triton X-100 and TnBP, most preferred by concentrations of 1% Triton X-100 and 0.3% TnBP for 4.5 to 8 hours to inactivate lipid coated viruses.

11. The method of claim 10, the detergents of the incubation mixture of which are removed by solid and liquid phase extraction.

12. The method of at least any one of claims 1 to 11 wherein at least one of the methods selected from the group consisting of UV-C treatment, heat-treatment, virus filtration and prion removal or inactivation is combined with a caprylate treatment of claim 1.

13. The method of claim 11, wherein the pH value upon solid phase extraction is adjusted to 6.7 to 6.9.

14. The method of claim 13, wherein the solution is submitted to the second anion-exchange chromatography.

15. The method of claim 14, wherein the pH value of the anion-exchanger flow-through is adjusted to 3.5 to 4.5, preferably to pH 4.0 ± 0.1.

16. The method of claim 15, wherein the IgG solution is contacted by a virus filter.

17. The method of claim 15, wherein the IgG solution is contacted by a nanofilter.

18. The method of claim 15 wherein the IgG solution is incubated for at least 24 hours, preferably at 37°C± 1.

19. The method of claim 15, wherein the IgG solution is concentrated to 5 or 10%.

20. The method of claim 19, wherein the osmolarity of the concentrate is adjusted to 200 to 400 mOsmol/kg by an appropriate additive.

21. The method of claim 20, wherein the IgG solution is pH adjusted to 3.5 to 6.0, preferred to a pH value of 4.0 to 5.5.

22. The method of claim 21 wherein the IgG solution is sterile filtered and filled in glass bottles or plastic containers.

23. An IgG containing fraction obtainable according one of the claims 1 to 22.